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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,948	10/28/2005	Peter Frank Ekhart	0470-050777	7559

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Webb Ziesenheim Logsdon Orkin & Hanson
436 Seventh Avenue
700 Koppers Building
Pittsburgh, PA 15219-1818

EXAMINER

BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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03/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,948

Applicant(s)

EKHART ET AL.

Examiner

LAYLA BLAND

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15-27, 29, 32-34, 36-43 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 13, 15-23, 34, 36-40 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-27, 29, 32, 33, 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 5, 2010 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed March 5, 2010, and amendment and response to the Final Office Action (mailed November 5, 2009), filed March 5, 2010 wherein claims 13, 15-21, 27, 29, 33, 34, and 37 are amended and claims 35, 44, and 45 are canceled. Claims 13, 15-27, 29, 32-34, 36-43, and 46 are pending.

Amended claims 13, 15-23, 34, 36-40, and 46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. Claims 13, 15-23, 34, 36-40, and 46 have been amended from a method of inducing satiety and satiation in a person to a method of thickening a composition. The method of inducing satiety and satiation in a person was previously examined, but methods of thickening a composition were not originally presented and have not been examined. The method of thickening a composition and the claimed food composition (claims 24-27, 29, 32, 33, and 41-43) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of thickening a composition could be used to prepare thickened compositions other than food products. Furthermore, the claimed food products could be prepared without acidifying the composition as required by the amended method claims. The previously claimed method of inducing satiety in a person and the method of thickening a composition as now claimed are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a different mode of operation, function, and effect because the amended claims are drawn to preparation of a composition and the previously submitted claims were drawn to a method of treating a person. The inventions are mutually exclusive because the method of thickening a composition requires addition of glucan to a composition and acidifying the composition, which is not required by the method of treatment; the previously claimed method of treatment requires administration to a person, which is not required by the amended claims. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13, 15-23, 34, 36-40, and 46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 24-27, 29, 32, 33, and 41-43 are examined on the merits herein.

In view of the cancellation of claims 35, 44, and 45, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment submitted March 5, 2010, the rejection of claims 13, 15-27, 29, and 32-46 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. The limitation "wherein the food composition has a texture that remains substantially unchanged by adding the α -glucan until the food composition enters a stomach of a person" was removed from the claims. Likewise, the rejection of claims 13, 15-27, 29, and 32-46 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-27, 29, 32, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Geel-Schutten et al. (Applied and Environmental Microbiology, 1999, pp. 3008-3014, Vol. 65(7), PTO-1449 submitted September 4, 2007) and Van Geel Schutten et al. (WO 01/90372 A1, November 29, 2001, PTO-1449 submitted September 4, 2007).

Van Geel-Schutten '99 teaches that polysaccharides are used as viscosifying, stabilizing, emulsifying, gelling, or water-binding agents in food industries, and that exopolysaccharides (EPS) produced from lactic acid bacteria are particularly desirable as food additives because lactic acid bacteria are food-grade organisms with GRAS status [page 3008, first paragraph]. Lactic acid bacteria and EPS contribute to the taste, smell, texture, and preservation of fermented milk products [page 3008, second paragraph]. EPS from lactic acid bacteria may be used as food-grade polysaccharides. One such EPS is produced from sucrose by the action of *Lactobacillus reuteri* [page

3008, third paragraph] (a preferred embodiment referred to as reuteran on page 5 of the instant specification). The glucan consists of terminal, 4-substituted, 6-substituted, and 4,6-disubstituted alpha-glucose in a molar ratio of 1.1 : 2.7 : 1.5 : 1.0 , indicating the presence of a branched glucan [page 3010, third paragraph].

Van Geel-Schutten '99 does not expressly teach a food composition comprising reuteran or the administration of such.

Van Geel Schutten '01 also teaches reuteran [see abstract and paragraph 0015]. EPS's act as prebiotic substrates, nutraceuticals, cholesterol lowering agents, or immunomodulants. High molecular weight polysaccharides such as cellulose, starch, pectin, alginate, carrageenan, gellan, and xanthan are all used in industrial and food applications, but lactic acid EPS's are more desirable than these because lactic acid bacteria have GRAS status [0002-0003]. Reuteran can be used as a prebiotic [0017].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a food composition comprising reuteran. Van Geel-Schutten '99 suggests the use of reuteran as a food additive which contributes to the taste, smell, texture, and preservation of milk products. Van Geel Schutten '01 further teaches that reuteran can be used as a prebiotic. Thus, the skilled artisan would prepare a food composition comprising reuteran in order to obtain a food product with better taste, smell, texture, and preservation, and/or to obtain a prebiotic composition.

Both references also teach the desirability of EPS produced by lactic acid bacteria (of which reuteran is one) as food-grade polysaccharide additives compared to other polysaccharides. Because Van Geel-Schutten '99 suggests EPS molecules for

enhancing taste, smell, preservation, or other qualities for which high-molecular-weight polysaccharides are used in food products, the skilled artisan would be motivated to prepare food products containing reuteran for those reasons. The cited references teach the function of reuteran in food products, so it would be within the skill of the skilled artisan to optimize the amount of reuteran for the desired taste, smell and texture.

The cited references do not address the thickening effect upon entering the stomach of a person. Claim scope is not limited by claim language that does not require steps to be performed or does not limit a claim to a particular structure. See MPEP 2111.04. In this case, "wherein the food composition is thickened upon entering a stomach of a person" does not limit the structure of the composition, but describes a property or function of the alpha-glucan. Further, MPEP 2112 states that the claiming of a new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, and that the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 103. In this case, "wherein the food composition is thickened upon entering a stomach of a person" describes a property or function of the alpha-glucan included in the composition. However, the prior art suggests food products containing the claimed alpha-glucan. MPEP 2112.01 states that if the structure recited in the prior art is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent.

Response to Arguments

Applicant argues that there is a substantial difference between milk and Slim-Fast drinks where reuteran was added, and that the result was unexpected. This argument is not persuasive because the prior art teaches that EPS such as reuteran are used as viscosifying agents and for enhancing the texture of foods. Thus, the skilled artisan would expect that a composition comprising reuteran would be thicker than the composition without reuteran. Thus, it is not clear why Applicant's results are unexpected, and Applicant offers no explanation of why the results are unexpected. MPEP 716.02(b) states that the evidence relied upon should establish that the differences in results are in fact unexpected and unobvious, and that Applicants have the burden of explaining any data they offer as evidence of non-obviousness. Furthermore, as noted on page 10 of Applicant's response, to establish unexpected results, Applicant must establish "that there actually is a difference between the results obtained through the claimed invention and those of the prior art." No comparison with the prior art has been made. Thus, although Applicant states that there is a "substantial difference," there is no evidence of "substantially improved results" because the data is not compared to the prior art so it is unclear what a substantial improvement would be. In other words, the claimed food product is substantially improved over what prior art product? And how is it improved? Applicant has shown that milk containing reuteran is more viscous than milk alone, but this is not considered unexpected or substantially improved because EPS's such as reuteran are used as viscosifying agents and for changing the texture of foods. For these reasons, the rejection is maintained.

Claims 24, 29, 33, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote et al. (US 5,786,196, July 28, 1998, of record) in view of Ritchey et al. (US 5,688,547, November 18, 1997, of record).

Cote et al. teach that high-molecular weight alternan consists primarily of α -1,3-linked and α -1,6-linked glucose residues with approximately 10% branching [column 1, lines 10-17]. Alternan is synthesized from sucrose via the enzyme alternan-sucrase [column 1, lines 23-24]. Alternan has potential as a substitute for gum arabic and for use as a bulking agent in foods, particularly as noncaloric, carbohydrate-based soluble food additives in artificially sweetened foods [column 1, lines 34-39].

Cote et al. do not exemplify a food composition comprising alternan.

Ritchey et al. teach an artificially sweetened meal replacement composition [see abstract], which comprises dietary fiber such as guar gum in an amount of 1-66% by weight, and 4-86% by weight of protein [column 4, lines 24-64]. In one example, gum arabic was used at 6.25% and whey protein concentrate at about 12% [column 5, Example 1]. The composition can be used as a shake or a mousse to induce satiety [see abstract].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a food composition comprising alternan and at least 1 wt% of a food protein. Cote suggests the use of alternan as an alternative to gum arabic and an additive to artificially sweetened foods. Ritchey teaches one example of

an artificially sweetened food which comprises gum arabic. Thus, the skilled artisan could conceive of replacing the gum arabic in Ritchey's composition with alternan.

The cited references do not address the thickening effect upon entering the stomach of a person. Claim scope is not limited by claim language that does not require steps to be performed or does not limit a claim to a particular structure. See MPEP 2111.04. In this case, "wherein the food composition is thickened upon entering a stomach of a person" does not limit the structure of the composition, but describes a property or function of the alpha-glucan. Further, MPEP 2112 states that the claiming of a new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, and that the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 103. In this case, "wherein the food composition is thickened upon entering a stomach of a person" describes a property or function of the alpha-glucan included in the composition. However, the prior art suggests food products containing the claimed alpha-glucan. MPEP 2112.01 states that if the structure recited in the prior art is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent.

Response to Arguments

Applicant argues that Cote is directed to products which have a low average molecular weight, which does not meet the limitation 10^5 Da. Indeed, portions of the Cole reference refer to low-molecular weight fractions. However, the reference teaches that "high-molecular weight alternan may be produced," and "this compound," as well as

low-molecular weight products produced therefrom, "lend themselves to potential commercial applications as substitutes for gum arabic, for use as bulking agents and extenders in foods and cosmetics, particularly as noncaloric, carbohydrate-based soluble food additives in artificially sweetened foods." [column 1, lines 24-39] Thus, Cole teaches the benefits of both the high-molecular weight alternan and the low-molecular weight alternan.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623